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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET N |
| 07/845,323 | 03/03/92 | WTC | 49670012 |

3M OFFICE OF INTELLECTUAL PROP. COORDINATE

P.O. BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER
HENRY T. T.

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1205 | 2 |

DATE MAILED: 05/21/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on _____ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, Form PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6. _____

Part II SUMMARY OF ACTION

1. Claims 1-33 are pending in the application.

Of the above, claims 16-31 are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-15 and 32-33 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other _____

EXAMINER'S ACTION

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Claims 1-33 are presented for examination.

As per the continued enforcement of the now final restriction requirement set forth in the Office action dated July 31, 1990 which was made final in the Office action of December 4, 1990, claims 16-31 remain withdrawn from consideration by the Examiner as provided for under 37 CFR 1.142(b).

Claims 1-5, 32 and 33 are herein acted upon the merits.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-15, 32 and 33 are rejected under 35 U.S.C. § 103 as being unpatentable over Gerster in view of Mahjour et al. and the combination of Kigasawa et al. and Lachman, each of record.

Gerster teaches that topical pharmaceutical formulations of the claim designated amine are known in the art for applicants' purpose.

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The differences between the above teaching and applicants' claimed invention are (1) Gerster fails to suggest that the claimed saturated and unsaturated fatty acids would be useful in such a topical formulation; and (2) Gerster fails to set forth the various claimed auxiliary agents, i.e. emollients, emulsifiers, thickeners and preservatives useful in such a topical formulation.

However, to the skilled artisan it would have been obvious to reconcile these differences and said artisan would have been motivated to do so in view of the following:

(1) Mahjour et al. teach that fatty acids of the type claimed are useful in combination with a variety of drugs including anti-infectives and said fatty acids are effective penetration enhancers for such drugs. Note column 2, line 39 and column 3, lines 5-13. That the skilled artisan would have been motivated to modify the topical composition of Gerster with the fatty acids of Mahjour is founded in Mahjour et al. at column 1, lines 56-60 where it is set forth that "it has been found that administration via penetration of the drug across a suitable membrane, e.g., the cutaneous barrier, is superior to other routes of administration, especially in terms of ease of administration and attainment of sustained release".

While isostearic acid is not highlighted by Mahjour et al., the reference does suggest employing long chain saturated and

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unsaturated fatty acids and thus it is deemed that the choice of any one particular fatty acid is a matter of choosing from obvious alternatives.

(2) Regarding the use of the claimed auxiliary agents, Lachman et al. at pages 220-229 and Kigasawa et al. at column 5, lines 11-14 and column 7, lines 4-49 teach that the various claim designated auxiliaries are well known for use in topical pharmaceutical formulations and thus the choice of the particular auxiliary agent to employ is deemed a matter of obvious alternatives to the skilled artisan.

This rejection duplicates that which was set forth at pages 2-4 of the Office action dated May 16, 1991 and is maintained for the reasons expressed at pages 2-3 of the Office action dated November 7, 1991.

Insofar as applicants have advanced no further arguments over those set forth in their response dated August 19, 1991, the propriety of this rejection is deemed to remain fully intact.

None of the claims are allowed.

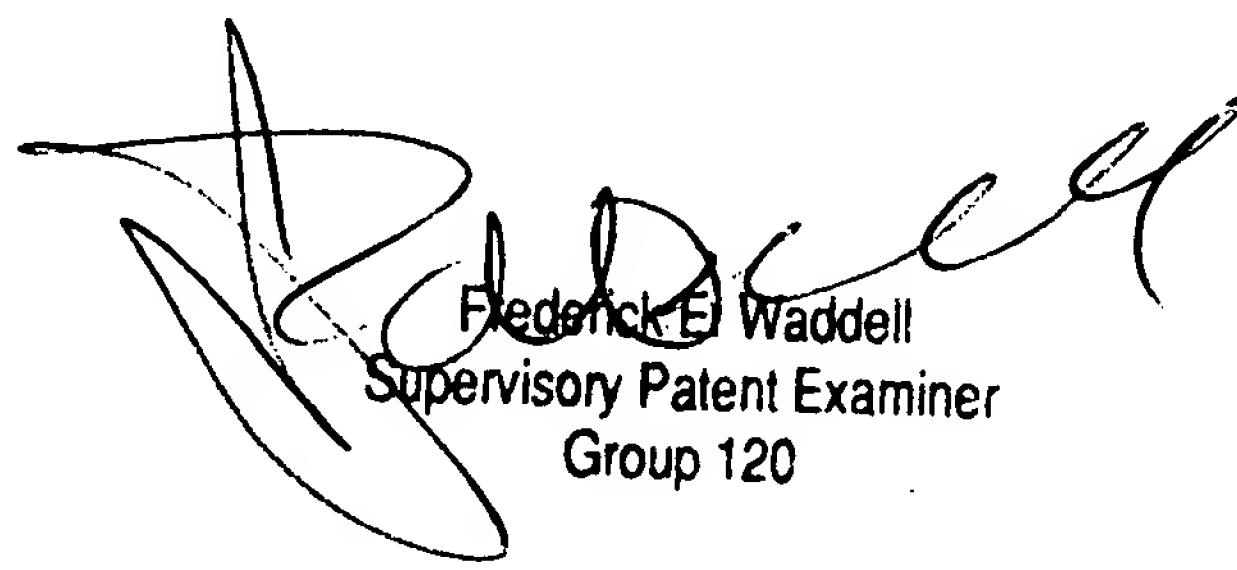
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

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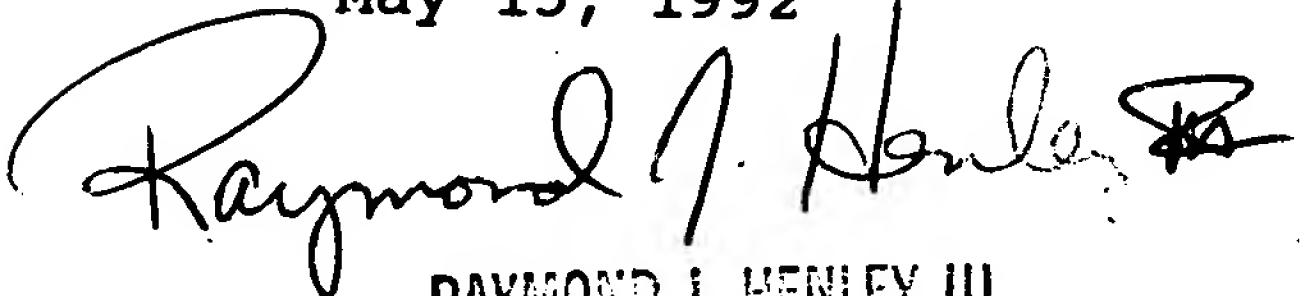
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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Frederick E. Waddell
Supervisory Patent Examiner
Group 120

Henley:st
May 15, 1992



RAYMOND J. HENLEY III
PATENT EXAMINER
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